

REMARKS

The Office Action requires an election under 35 U.S.C. §121 from among the following groups:

I: claims 1-4, 8-10, 12-15, 17-20 and 31, drawn to a polynucleotide comprising at least two repeats of a hypoxia response element (HRE) and separated by a spacer of at least 20 contiguous nucleotides, or the polynucleotide is further operably linked to a nucleic acid of interest (NOI) for expression in host cells, and a method of producing a viral strain by using said polynucleotide;

II: claim 5, drawn to a polynucleotide comprising at least four repeats of a hypoxia response element (HRE) and separated by a spacer of at least 20 contiguous nucleotides; and

III: claims 6, 7 and 11, drawn to a polynucleotide comprising at least six repeats of hypoxia response element (HRE) and separated by a spacer of at least 20 contiguous nucleotides.

Group I is elected, with traverse, for further prosecution in this application. Applicants reserve the right to file divisional applications to non-elected subject matter. In addition, the Examiner is thanked for pointing out the inconsistencies in claims 21-27. These claims have been amended such that they all depend, directly or indirectly, on claim 1. Therefore, it is requested that claims 21-27 be rejoined with the claims of group I. No new matter is added.

The Office Action further required an election of species. As to a spacer sequence, HRE sequence and NOI, Applicants elect SEQ ID NO:10, SEQ ID NO:9 and HIF1- α , respectively, with traverse.

It is Applicants' understanding that, upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all of the limitations of an allowed generic claim, as provided by 37 C.F.R. 1.141. It is also understood that the Examiner can broaden the search to include other species, e.g., upon determining that a species is allowable, or as discussed herein, when there is a relationship among the species and/or number of species is not too great.

In this regard, M.P.E.P. § 808.01(a) states that "where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention" is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate. Moreover, MPEP 803.02 specifically provides that members of a claimed *Markush* group (e.g. as in

claim 3) must be searched and examined together, if they are not too many in number.

Examination of the generic claims, without election, does not impose a serious burden on the Examiner. For example, SEQ ID NO:10 is identical to nucleotides 7-18 of SEQ ID NO:11; therefore, an examination of SEQ ID NO:11 would inevitably encompass a search that included SEQ ID NO:10. Likewise, SEQ ID NO:2 is identical to nucleotides 4-22 of SEQ ID NO:1. No election should, therefore, be required.

The Office Action alleges that the claims of the present invention are not linked so as to form a single inventive concept under PCT Rule 13.1. Allegedly, the claims of the present invention lack the same or corresponding special technical features as required under PCT Rule 13.2 because the special technical feature of the Group I claims is allegedly present in the prior art. The special technical feature of the group I claims is HRE repeats with a spacer of at least 20 nucleotides between the hypoxia-inducible factor consensus binding sites. This feature is not found in the prior art, and links the claims of groups I-III.

Enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made in the Office Action and there are relationships between all of the claimed combinations. Indeed, the search and examination of each combination is likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigates against restriction.

In view of the above, reconsideration and withdrawal of the Requirement for Restriction are requested, and an early action on the merits earnestly solicited.

Respectfully submitted,

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